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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,207	12/01/2000	Yoshiyuki Nagai	50026/005002	4421
31496	7590	11/04/2003	EXAMINER	
SMITH PATENT CONSULTING CONSULTING, LLC			MOSHER, MARY	
P.O. BOX 2726			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22301			1648	
DATE MAILED: 11/04/2003				

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>	
	09/728,207	NAGAI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 7/18/2003, 4/18/2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-18,20,22,27 and 28 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-18,20,22,27 and 28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. 09/071,591.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/2003 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 11-13, and 27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Park et al (Proc. Natl. Acad. Sci. USA 88:5537-5541, 1991).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 27 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hsu et al (*Virology* 146:38-49, 1985), Ogura et al (*Journal of General Virology* 55:469-473, 1981), or Middleton et al (*Virology* 176:656-657, 1990). Hsu teaches Sendai virus genomes with NP, P, or L deleted or modified. Ogura teaches Sendai virus with a modified P gene. Middleton teaches Sendai virus genomes with NP, P, and L genes modified. The references do not call the viruses or their genomes vectors, and do not make them by a recombinant DNA process. However, the specification does not define a viral vector in any way that distinguishes it from a conventional Sendai virus, and a recombinant DNA process can be used to make a virus with characteristics identical to a virus made by conventional propagation methods. Therefore, the claims read upon products indistinguishable from the prior art viruses and their genomes. Patent owner's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based

on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-11 13-18, 20, 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10, 26-47 of copending Application No. 09/070,938. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant dissemination-

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defective Sendai virus vector and associated products and methods of use overlap in scope with the broadly claimed recombinant Sendai virus vector and associated products and methods of use claimed in this application.

Claims 1, 3-6, 11-14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 11, 12, 14, 20, 21 of copending Application No. 09/132,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a chemokine gene and methods of use overlap in scope with the broadly claimed recombinant Sendai virus vector and methods of use claimed in this application.

Claim 7 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 8 of copending Application No. 09/471,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the instant claims encompass the subject matter of the claims previously allowed in the copending application.

Claims 1, 3-6, 13, 14, 16, 17, 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8 of copending Application No. 09/702,498. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims read upon recombinant Sendai vector with an insert prior to the NP gene.

Claims 1, 3-6, 13, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 16-19, 46-49, 54-57 of copending Application No. 09/823,699. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with HIV genes overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 3-6, 13, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 09/843,922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to negative-sense RNA viral vector overlap in scope with the recombinant Sendai virus vector. Although copending claim 16 does not recite Sendai virus, it is an obvious embodiment because other claims specifically recite Sendai virus, e.g. claim 15.

Claims 1, 3-6, 12, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 8 of copending Application No.10/111,356. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a CTFR gene overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 3-6, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-13 of copending Application No. 10/181,646. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a foreign

gene overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 3-6, 13, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of copending Application No. 10/312,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with a gene for a renal cell overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Claims 1, 3-5, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4 of copending Application No. 10/316,530, in view of Gotoh et al (Virology 171:434-443, 1989). Although the conflicting claims are not identical, they are not patentably distinct from each other because Gotoh teaches that a ribonucleoprotein complex was known to be involved in recovery of infectious Sendai virus genomes in the prior art. Therefore claims to a Sendai vector are seen as obvious over claims to a complex containing the Sendai vector.

Claims 1, 3-6, 13, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7 of copending Application No. 10/316,535. Although the conflicting claims are not identical, they are not patentably distinct from each other because in view of Gotoh et al (Virology 171:434-443, 1989). Although the conflicting claims are not identical, they are not patentably distinct from each other because Gotoh teaches that a ribonucleoprotein complex was known to be involved in recovery of infectious Sendai

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virus genomes in the prior art. Therefore claims to a Sendai vector are seen as obvious over claims to a complex containing the Sendai vector.

Claims 1, 3-6, 13, 14, 16, 17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7 of copending Application No.10/444,661. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope, such that the copending claims to recombinant Sendai virus vector with an angiogenic gene overlap in scope with the broadly claimed recombinant Sendai virus vector claimed in this application.

Applications 09/720,979 and 10/398,598 are not currently available to the examiner. However, provisional double patenting rejections may be made over the claims in these applications when they become available.

The above rejections are all provisional obviousness-type double patenting rejections, because the conflicting claims have not in fact been patented.

Claims 7-9, 11, 12, 20, 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,514,728. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented methods and products, or because the patent claims recite a process using products that are encompassed by the instant claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926. The examiner can normally be reached on M-T and alternate F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

11/3/03

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800 7600